Massachusetts Department of Public Health
Division of Epidemiology and Immunization

VariZIG™

Investigational New Drug Available for Postexposure Prophylaxis of Varicella

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On October 27, 2004, the Advisory Committee on Immunization Practices (ACIP) was informed by the only U.S.-licensed manufacturer of varicella zoster immune globulin (VZIG) that the company had discontinued production of VZIG. In February 2006, an investigational VZIG product, VariZIG™ (manufactured by Cangene Corporation and distributed by FFF Enterprises) became available under an investigation new drug application (IND). This product is immune globulin with high levels of antibody against varicella virus. Guidance on the indication and use of VariZIG™ were also published in the MMWR (CDC. MMWR 2006;55) which can be found at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5508a5.htm.

The expanded access protocol has received central institutional review board (IRB) approval at Cangene Corporation. With this central IRB approval, FDA does not require additional approval at the treatment site. However, some treatment sites might require notification of the site's IRB prior to participation.

As with any product used under IND, patients must be informed of potential risks and benefits and must give informed consent before receiving the product. Sample assent and consent forms, as well as the expanded access protocol and investigator's brochure, are available from FFF Enterprises (800-843-7477).

Patients with Indications for Use of Investigational VariZIG™:

- Without evidence of immunity to varicella (see Proof of Immunity to Varicella, next page)
- At high risk for severe disease or complications:
  - Immunocompromised patients
  - Neonates whose mothers have signs and symptoms of varicella around the time of delivery
  - Premature infants born at ≥ 28 weeks of gestation who are exposed during the neonatal period and whose mothers do not have evidence of immunity
  - Premature infants born at < 28 weeks of gestation or who weigh ≤ 1,000 g at birth and were exposed during the neonatal period, regardless of maternal history of varicella disease or vaccination
- Pregnant women
- Have been exposed to varicella
- Have given informed consent

Timing of Administration of VariZIG™

- Maximum benefit when administered as soon as possible after exposure, but effective if administered as late as 96 hours after exposure (125 units/10 kg up to maximum 625 units)
- If administration of VariZIG™ does not appear possible within 96 hours of exposure, administration of immune globulin intravenous (IGIV) within 96 hours of exposure should be considered as an alternative
- For pregnant women who cannot receive VariZIG™ within 96 hours of exposure, clinicians may choose either to administer IGIV (400 mg/kg) once within 96 hours of exposure or closely monitor for sign and symptoms of varicella and treat with acyclovir if illness occurs

How to Obtain Investigational VariZIG™

VariZIG™ can be requested only from FFF Enterprises (phone, 800-843-7477; fax, 800-418-4333). A sample release form can be found at http://www.fda.gov/cber/infosheets/mphvzig020806form.pdf or obtained from FFF Enterprises at 800-843-7477.

Proof of Immunity to Varicella[1]
• Documentation of age-appropriate, prior vaccination against chickenpox (1 dose at 1–12 years of age or 2 doses ≥ 1 month apart at ≥ 13 years of age), or • Born in the U.S. before 1966 (regardless of history of chickenpox), or • Born outside the U.S. before 1966 with a reliable history of chickenpox (a recollection or record of past disease from the person, parent or physician is sufficient[2,3]), or • Born in or after 1966 (regardless of country of birth) with a reliable history of chickenpox (as described above), or • A reliable history of herpes zoster based on health-care provider diagnosis, or • Serologic proof of immunity[4].
[1]Bone marrow transplant recipients should be considered susceptible *regardless* of past history of disease. [2] A self-report of typical disease is sufficient for college students, as well as for staff in all settings. The *exception* is that a physician-certified history of disease is required for students in child care, preschool or grades K-12. [3] For those with a history of an atypical, mild case, seek an epidemiological link to a typical varicella case [e.g. case is/was in the context of an outbreak or there was a case in the household or classroom within 3 weeks of illness] or laboratory confirmation of prior infection at time of acute illness. If such documentation is lacking, persons should not be considered as having a valid history of disease because other diseases may mimic mild atypical varicella. [4] Or laboratory-confirmed at time of acute illness.